42. (Newly Added) An isolated nucleic acid molecule of claim 15, wherein said transcription is ventricle preferred.

REMARKS

I. Introductory Comments

Claims 1-15 are currently pending in the application. Claims 16-37 have been canceled pursuant to the Examiner's restriction requirement. Claims 4, 5, 12, 13, and 15 have been amended. Claims 38-42 are newly added. Reconsideration of the Application is respectfully requested.

II. Examiner Interview Summary

The undersigned thanks Examiners Montanari and Shukla for the courtesies extended during the personal interview with myself and David Mancino conducted on August 25, 2005. During the interview, the undersigned discussed claims 9-15 with respect to 35 U.S.C. § 112, first paragraph regarding written description and claims 4-5 and 12-13 with respect to 35 U.S.C. § 112, first paragraph regarding enablement.

The undersigned presented a description of the functional limitation provided by limiting the claim to those nucleotide sequences having at least 95% identity to SEQ ID NO:1, wherein the nucleotide sequence is capable of initiating transcription in cardiac tissue. The undersigned and the examiners discussed the suggestion raised in the Office Action that all species of the claimed genus would share the characteristic of being capable of initiating transcription in cardiac tissue. The Examiners indicated that should the specification or the art teach a region or regions of the nucleotide sequence set forth in SEQ ID NO:1 that were it or they altered would affect the cardiac-tissue preference of the promoter, the functional limitation might be considered sufficiently described.

While no agreement with respect to claims 9-15 was reached, Examiners Montanari and Shukla graciously indicated that they would consider amendments in light of the discussion.

Next, the undersigned discussed claims 4-5 and 12-13 with respect to 35 U.S.C. § 112, first paragraph regarding enablement for any host cell comprising an expression

cassette of the invention, particularly with regards to somatic cells transformed *in vivo*. The undersigned highlighted teachings within the specification that discuss the somatic cells of transgenic mice made by the applicant. Examiners Montanari and Shukla reiterated that the claims might be construed to read on gene therapy. Examiners Shukla and Montanari indicated that claims directed toward isolated host cells comprising an expression cassette of the invention would be considered proper. While no agreement with respect to these claims was reached, Examiners Montanari and Shukla graciously indicated that they would consider amendments in light of the discussion.

Applicants gratefully acknowledge Examiners Montanari and Shukla's gracious indication that claims 1-3 and 6-8 are directed to allowable subject matter.

The undersigned thanks Examiner Montanari for the courtesies extended during a personal interview with myself conducted on November 7, 2005. During the interview, the undersigned discussed the objection to the specification. While no agreement was reached, the undersigned appreciates the Examiner's explanation.

III. Objections to the Specification

The Office action objects to the specification of the disclosure because information pertaining to the deposit of plasmids comprising SEQ ID NO:1 of the invention with the Patent Depository of the American Type Culture Collection has been left blank. Applicants note that "[w]henever a biological material is specifically identified in an application for a patent as filed, an original deposit thereof may be made at any time [...] during pendency of the application for patent" 37 C.F.R. §1.804(a). Applicant respectfully assures the Examiner that either a deposit will be made or the specification will be amended prior to payment of the issue fee. Reconsideration and the withdrawal of the objections of record pertaining to the specification of the disclosure are respectfully requested.

IV. Rejections under 35 U.S.C. § 112

Claims 4-5 and 12-13 stand rejected under the first paragraph of 35 U.S.C. § 112 as allegedly lacking "enablement for any host cells stably transformed with an expression cassette" (p.3) comprising a nucleotide sequence of the invention and suggesting that this "embodiment reads on gene therapy" (p. 4). Claims 4-5 and 12-13 have been currently amended to make abundantly clear that each host cell is an isolated host cell. Accordingly, claims 4-5 and 12-13, as amended, do not read on gene therapy.

In light of the current amendments, Applicant submits that claims 4-5 and 12-13 are sufficiently enabled by the current specification and respectfully requests that the rejection be withdrawn.

V. Rejections under 35 U.S.C. § 112

Claims 9-15 stand rejected under the first paragraph of 35 U.S.C. § 112 as allegedly failing to comply with the written description requirement. The Office Action states that other than nucleotide sequence "the only characteristic described is that the nucleic acid is capable of initiating transcription in cardiac tissue," but suggests that "all species of the claimed genus [that is, an isolated nucleic acid molecule having a nucleotide sequence having at least 95% identity to the sequence set forth in SEQ ID NO:1, wherein said nucleotide sequence is capable of initiating transcription in cardiac tissue, and an expression cassette comprising such an isolated nucleic acid molecule, a vector comprising such an expression cassette, and a host cell stably transformed with such an expression cassette], will have this characteristic." Therefore, the Office Action alleges that limiting the claim to those nucleotide sequences having at least 95% identity to the sequence set forth in SEQ ID NO:1 wherein the capability of initiating transcription in cardiac tissue is retained fails to provide a functional attribute that would distinguish different members of the claimed genus. During the August 25, 2005 telephone interview, it was suggested that were the specification or the art to teach regions of SEQ ID NO:1 that were targets for nucleotide changes that would alter the ability of the nucleotide sequence to initiate transcription in cardiac tissue and yield a nucleotide sequence having at least 95% identity to the nucleotide sequence set forth in

SEQ ID NO:1, that the capability "of initiating transcription in cardiac tissue" would provide a functional attribute that would distinguish different members of the claimed genus.

Transcriptional regulatory regions are known in the art and are described in paragraphs 56 and 61-62 of the specification. The TATAA box is a well-characterized, art-recognized eukaryotic transcriptional regulatory region (see for example Suzuki *et al.* (1989) An Introduction to Genetic Analysis W.H. Freeman & Co. 4th ed. p.465 and Friefelder (1987) Molecular Biology Jones & Bartlett Publishers, Inc. 2nd ed p.348). Alteration of a eukaryotic transcriptional regulatory region such as the TATAA box (nucleotides 4633- 4638 of SEQ ID NO:1) would impinge the nucleotide sequences' capability of initiating transcription and would have at least 95% identity to SEQ ID NO:1. Alteration of nucleotides involved in cardiac tissue preference would affect the capability of initiating transcription in a tissue-preferred manner.

Examiner's attention is respectfully drawn to ¶61 on pages 24-25 of the originally filed specification wherein various cardiac-tissue preferred promoters are described and articles encompassing them are incorporated by reference. Grepin *et al.* (1994) *Mol. Cell Biol.* 14:3115-29 discusses cardiac muscle transcription of the A- and B-type natriuretic peptide genes and identifies particular sequences involved in cardiac-preferred transcription. Majalahti-Palviainen *et al.* (2000) *Endo.* 141:731-740 discusses cardiac preferred transcription by the salmon cardiac peptide promoter and identifies particular sequences involved in cardiac-preferred transcription. Charron *et al.* (1999) *Mol. Cell Biol.* 19:4355-4365 discusses cardiac preferred transcription modulated by the GATA-4 and GATA-6 transcription factors and the regulatory sequence elements to which the GATA transcription factors bind. Additional cardiac preferred regulatory regions are described in Rahkonen, *et al.* (2002) *Biochim Biophys Acta* 1577:45-52; Dellow, *et al.* (2001) *Cardiovasc. Res.*50:3-6; and Kiewitz, *et al.* (2000) *Biochim Biophys Acta* 1498:207-19. These cardiac-preferred regulatory regions include GATAA, CACC box, E2A, and Ap-1-like sequences similar to those present in SEQ ID NO:1 of the present invention. Thus, it is respectfully submitted that the specification teaches regions of SEQ ID NO:1 that function in tissue-preferred transcription. In view of the teachings found in

the specification, it is evident that limiting the claimed nucleotide sequences having at least 95% identity to the nucleotide sequence set forth in SEQ ID NO:1 to those with the capability "of initiating transcription in cardiac tissue" provides a functional attribute that distinguishes different members of the claimed genus. Thus, claims 9-14 comply with the written description requirement of 35 U.S.C. § 112. Applicant respectfully requests that the rejection be withdrawn.

Claim 15 has been rewritten in independent form to incorporate all the elements and limitations of claim 9 plus the functional limitation that transcription is inducible. New claims 38-42 incorporate all the elements and limitations of claims 10-14 and depend from claim 15. It is respectfully submitted that sufficient basis for these claims is present in the application as originally filed.

VI. Allowable Subject Matter

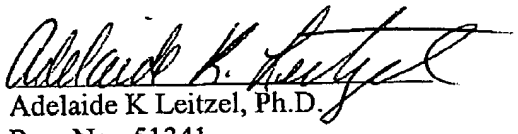
The Office action states that no claims are allowed; however, no rejections were raised to claims 1-3 and 6-8. The Examiner's comments during the August 25, 2005 telephone interview that claims 1-3 and 6-8 are directed to allowable subject matter are gratefully acknowledged.

VII. Conclusion

In light of the foregoing, it is respectfully submitted that claims 1-15 and 38-42, now pending, are enabled and sufficiently described, and in condition for allowance. Reconsideration and withdrawal of the rejections of record is respectfully requested.

If the Examiner wishes to discuss any aspect of this response, please contact the undersigned at the telephone number provided below.

Respectfully submitted,



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